

I acknowledge the duty to disclose information that is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (reprinted below):

**§ 1.56 Duty to disclose information material to patentability.**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

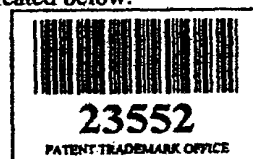
Albrecht, John W.	Reg. No. 40,481
Ali, M. Jeffer	Reg. No. 46,359
Anderson, Gregg I.	Reg. No. 28,828
Batzli, Brian H.	Reg. No. 32,960
Beard, John L.	Reg. No. 27,612
Berns, John M.	Reg. No. 43,496
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Branch, John W.	Reg. No. 41,633
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Kowalchyk, Katherine M.	Reg. No. 36,848
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Nichols, A. Shane	Reg. No. 43,836
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Phillips, Bryan K.	Reg. No. P-46,990
Phillips, John B.	Reg. No. 37,206
Prendergast, Paul	Reg. No. 46,068
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Schuman, Mark D.	Reg. No. 31,197
Schumann, Michael D.	Reg. No. 30,422
Scull, Timothy B.	Reg. No. 42,137
Sebald, Gregory A.	Reg. No. 33,280
Skoog, Mark T.	Reg. No. 40,178
Spellman, Steven J.	Reg. No. 45,124
Stoll-DeBell, Kirstin L.	Reg. No. 43,164
Sumner, John P.	Reg. No. 29,114
Swenson, Erik G.	Reg. No. 45,147
Tellekson, David K.	Reg. No. 32,314
Trembath, Jon R.	Reg. No. 38,344
Tuchman, Ido	Reg. No. 45,924
Tunheim, Marcia A.	Reg. No. 42,189
Underhill, Albert L.	Reg. No. 27,403
Vandenburgh, J. Derek	Reg. No. 32,179
Wahl, John R.	Reg. No. 33,044
Weaver, Karrie G.	Reg. No. 43,245
Welter, Paul A.	Reg. No. 20,890
Whipps, Brian	Reg. No. 43,261
Whitaker, John E.	Reg. No. 42,222
Wickhem, J. Scot	Reg. No. 41,376
Williams, Douglas J.	Reg. No. 27,054
Withers, James D.	Reg. No. 40,376
Witt, Jonelle	Reg. No. 41,980
Wu, Tong	Reg. No. 43,361
Xu, Min S.	Reg. No. 39,536
Zeuli, Anthony R.	Reg. No. 45,255

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant & Gould P.C. to the contrary.

Please direct all correspondence in this case to Merchant & Gould P.C. at the address indicated below:

Merchant & Gould P.C.  
P.O. Box 2903  
Minneapolis, MN 55402-0903



I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2	Full Name Of Inventor	Family Name LEE	First Given Name Tae-Yoon	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
1	Mailing Address	Address Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu		City Daegu-shi
Signature of Inventor 201:			Date: January 22, 2001	

2	Full Name Of Inventor	Family Name KIM	First Given Name Sung-Kwang	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
2	Mailing Address	Address Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu		City Daegu-shi
Signature of Inventor 202:			Date: January 22, 2001	

2	Full Name Of Inventor	Family Name LEE	First Given Name Jong-Seok	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
3	Mailing Address	Address Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu		City Daegu-shi
Signature of Inventor 203:			Date: JANUARY 22, 2001	

2	Full Name Of Inventor	Family Name LEE	First Given Name Jai-Youl	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
4	Mailing Address	Address 1370, Sankok-dong, Book-gu		City Daegu-shi
Signature of Inventor 204:			Date: January 22, 2001	

**SMALL BUSINESS****VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 C.F.R. 1.9(f)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- a) ☐ the owner of the small business concern identified below:  
b) ☐ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: BIOGENIA CO., LTD.  
ADDRESS OF CONCERN: Owner Venture Bldg. Ste 409  
1661, Bongchun-dong, Kwanack-gu  
Seoul, KOREA

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. 121.801-805, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE by inventor(s) LEE, TAE-YOON; KIM, SUNG-KWANG; LEE, JONG-SEOK; LEE, JAI-YOUL described in

- a) ☐ the specification filed herewith.  
b) ☐ provisional application serial no \_\_\_\_\_, filed \_\_\_\_\_.  
c) ☒ non-provisional application serial no \_\_\_\_\_, filed \_\_\_\_\_.  
d) ☐ patent no. \_\_\_\_\_, issued \_\_\_\_\_.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. 1.9(e) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

NAME: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
a) ☐ INDIVIDUAL b) ☐ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION  
NAME: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
a) ☐ INDIVIDUAL b) ☐ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.27(g)(2))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

NAME: \_\_\_\_\_  
TITLE: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
SIGNATURE: TW2 Date: January 22, 2001



M&amp;G 12777.8US01

**INDEPENDENT INVENTOR(S)****VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 C.F.R. 1.9(f)) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE described in

- a) ☐ the specification filed herewith.  
 b) ☐ provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.  
 c) ☒ non-provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.  
 d) ☐ patent no. \_\_\_\_\_, issued \_\_\_\_\_.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. 1.9(e) if that person has made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e)

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- a) ☐ no such person, concern, or organization  
 b) ☒ persons, concerns or organizations listed below\*

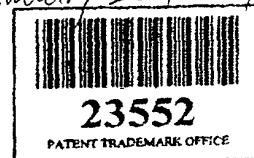
NAME	BIOGENIA CO., LTD.,		
ADDRESS	Owner Venture Bldg. Ste 409, 1661, Bongchun-dong, Kwanack-gu, Seoul, KOREA		
	a) <input type="checkbox"/> INDIVIDUAL	b) <input checked="" type="checkbox"/> SMALL BUSINESS CONCERN	c) <input type="checkbox"/> NONPROFIT ORGANIZATION
NAME	LEE, Tae-Yoon		
ADDRESS	Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu, Daegu-shi, KOREA		
	a) <input checked="" type="checkbox"/> INDIVIDUAL	b) <input type="checkbox"/> SMALL BUSINESS CONCERN	c) <input type="checkbox"/> NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.27(g)(2))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

	KIM, Sung-Kwang	LEE, Jong-Seok	LEE, Jai-Youl
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Signature of Inventor	Signature of Inventor	Signature of Inventor	Signature of Inventor

Date	Date	Date	Date
	<i>January 22, 2001</i>	<i>January 22, 2001</i>	<i>January 22, 2001</i>



MERCHANT &amp; GOULD P.C.

M&amp;G: 12777 8US01

**INDEPENDENT INVENTOR(S)****VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 C.F.R. 1.9(f)) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE described in

- a) ☐ the specification filed herewith.  
 b) ☐ provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.  
 c) ☒ non-provisional application serial no. \_\_\_\_\_, filed \_\_\_\_\_.  
 d) ☐ patent no. \_\_\_\_\_, issued \_\_\_\_\_.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. 1.9(c) if that person has made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

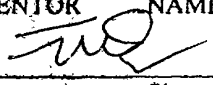
- a) ☐ no such person, concern, or organization  
 b) ☒ persons, concerns or organizations listed below\*

NAME BIOGENIA CO., LTD.,  
 ADDRESS Owner Venture Bldg. Ste 409, 1661, Bongchun-dong, Kwanack-gu, Seoul, KOREA  
 a) ☐ INDIVIDUAL b) ☒ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

LEE, Tae-Yoon

NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
			
Signature of Inventor	Signature of Inventor	Signature of Inventor	Signature of Inventor
Date	Date	Date	Date
January 22, 2001			

